

# C L A I M S

1. Rosiglitazone maleate crystalline form I having a powder diffraction spectrum to X-rays with the following principal absorptions:

Angle (2 $\theta$ )	d (Å)	Rel. Intens. (I/I <sub>0</sub> )
7.570	11.6687	2.4
8.580	10.2972	5.2
9.355	9.4458	8.1
14.005	6.3183	6.4
15.125	5.8529	41.4
16.005	5.5330	100.0
17.160	5.1631	10.0
18.625	4.7601	31.0
20.240	4.3838	6.8
21.000	4.2268	13.9
21.990	4.0387	32.9
22.785	3.8996	12.1
23.585	3.7691	30.0
25.055	3.5512	60.4
26.480	3.3632	18.0
28.425	3.1374	11.9
28.905	3.0863	8.6
30.430	2.9351	8.1
31.395	2.8470	6.7
32.145	2.7823	8.9
33.990	2.6353	9.3

2. Rosiglitazone maleate crystalline form I having a powder diffraction spectrum to X-rays as shown in Figure 4.

3. Rosiglitazone maleate crystalline form I having a DSC graph as shown in Figure 1.
4. Rosiglitazone maleate crystalline form I having an IR spectrum as shown in Figure 7.
5. Rosiglitazone maleate crystalline form II having a powder diffraction spectrum to X-rays with the following principal absorptions:

Angle (2 $\theta$ )	d (Å)	Rel. Intens. (I/I <sub>0</sub> )
7.615	11.5998	7.4
8.985	9.8340	4.8
9.740	9.0733	9.3
13.635	6.4889	11.6
14.015	6.3138	7.1
15.320	5.7788	100.0
17.105	5.1796	43.8
17.910	4.9485	21.8
19.255	4.6058	16.7
20.330	4.3646	27.8
20.765	4.2741	21.7
22.285	3.9859	37.8
23.730	3.7464	14.1
24.610	3.6144	37.7
25.485	3.4922	27.0
27.030	3.2960	24.4
27.440	3.2477	17.0
28.135	3.1690	8.7
29.225	3.0533	12.7
29.905	2.9854	24.1
31.645	2.8251	11.5

6. Rosiglitazone maleate crystalline form II having a powder diffraction spectrum to X-rays as shown in Figure 5.
7. Rosiglitazone maleate crystalline form II having a DSC graph as shown in Figure 2.
8. Rosiglitazone maleate crystalline form II having an IR spectrum as shown in Figure 8.
9. Rosiglitazone maleate crystalline form III having a powder diffraction spectrum to X-rays with the following principal absorptions:

Angle (2 $\theta$ )	d (Å)	Rel. Intens. (I/I <sub>0</sub> )
7.555	11.6918	6.2
8.895	9.9333	9.0
9.670	9.1388	12.1
13.050	6.7785	5.7
15.030	5.8896	55.2
15.345	5.7694	100.0
16.970	5.2205	40.3
17.300	5.1216	30.3
17.810	4.9761	34.7
19.105	4.6416	16.9
20.060	4.4227	33.0
20.745	4.2782	27.4
22.190	4.0028	51.0
24.400	3.6450	52.1
25.205	3.5304	36.7
25.830	3.4464	13.4
26.675	3.3391	46.0
27.360	3.2570	26.3
27.985	3.1857	13.2
29.795	2.9961	35.5
30.685	2.9112	11.4

10. Rosiglitazone maleate crystalline form III having a powder diffraction spectrum to X-rays as shown in Figure 6.

11. Rosiglitazone maleate crystalline form III having a DSC graph as shown in Figure 3.

12. Rosiglitazone maleate crystalline form III having an IR spectrum as shown in Figure 9.

13. Pharmaceutical compositions containing rosiglitazone maleate crystalline form I according to claim 1 together with pharmaceutically acceptable excipients and/or adjuvants.
14. Pharmaceutical compositions containing rosiglitazone maleate crystalline form II according to claim 5 together with pharmaceutically acceptable excipients and/or adjuvants.
15. Pharmaceutical compositions containing rosiglitazone maleate crystalline form III according to claim 9 together with pharmaceutically acceptable excipients and/or adjuvants.
16. A process for the crystallization of rosiglitazone maleate form I characterized in that it comprises the following steps:
  - a. heating to reflux an approximately equimolar mixture of rosiglitazone base and maleic acid in a solvent selected from alcohols, esters and/or ethers;
  - b. cooling said mixture to ambient temperature;
  - c. filtration and washing of the product;
  - d. desiccation.
17. A process according to claim 16, characterized in that said alcohols and/or esters are selected from isopropanol, ethyl acetate, isopropyl acetate and/or THF.
18. A process for the crystallization of rosiglitazone maleate form II, characterized in that it comprises the following steps:

a. heating to reflux an approximately equimolar mixture of rosiglitazone base and maleic acid in water;

b. cooling said mixture to ambient temperature;

c. filtration and washing of the product;

d. desiccation.

19. A process for the crystallization of rosiglitazone maleate form II, characterized in that it comprises the following steps:

a. heating to reflux an approximately equimolar mixture of rosiglitazone base and maleic acid in a water:ethanol mixture from 1.5 : 1 to 2.5 : 1 by volume;

b. cooling said mixture to ambient temperature;

c. filtration and washing of the product;

d. desiccation.

20. A process for the crystallization of rosiglitazone maleate form III characterized in that it comprises the following steps:

a. heating to reflux a mixture approximately containing rosiglitazone base and a double molar quantity of maleic acid in absolute ethanol and/or denatured ethanol;

b. cooling said mixture to ambient temperature;

c. filtration and washing of the product;

d. desiccation.

21. A process according to claims 16 to 20, characterized in that said mixture is maintained

under reflux for a time ranging between about 20 and 40 minutes.